

REMARKS

The following claims are in prosecution, Claims 1 to 2, 5, and 8 to 24. Claims 8 and 17 have been cancelled and claim 1 has been amended to further clarify the invention.

1. The Examiner rejected Claims 1-2, 5 and 8 to 24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons noted on page 2, paragraph 2.

The Examiner states, “nowhere in the specification one can find what swellable composition is applied.”

The applicant respectfully disagrees with this conclusion. In that “swellable composition” is noted at: Page 5, line 24; line 27; Page 6, line 17; line 26; Page 7, line 4; Page 8, line 9; line 26, to Page 9, line 7; Page 10, line 19; Page 11, line 3; line 16; line 25; Page 12, line 1; line 17; Page 13, line 1; Page 16, line 7. All of these references occur in the specification with detailed explanation therein.

As to what “swellable composition” is applied, this is defined on Page 8, line 26 to Page 9, line 7. Reference is made to US patents and other patent documents. These reference are incorporated by reference. For example, US Patent 5,770,229 clearly defines swelling polymer gels.

The Examiner further states, “the specification only refers to some prior art and does not specifically disclose what compositions come under swellable compositions.”

Again, the Applicant disagrees with this conclusion. The definition of “swellable composition” is given in the specification and reference is made to many patent documents. It is clearly asserted that this description is in fact sufficient because these references were incorporated by reference, meaning these teachings are considered a part of the disclosure.

On page 3 of the office action, the Examiner states, “substance is a form of liposomes” but this, in fact, was not stated by the Applicant. The Applicant stated, “In one preferred embodiment, the substance is a form of microspheres or liposomes.” Therefore, the “substance is ... liposomes.” The subsequent conclusion has merely been made to support the Examiner’s own theory: the liposome itself is a swellable composition. As stated in claim 13, said “swellable composition are polymers” and as stated in claim 18, “said polymers are encapsulated in

liposomes.” and therefore, the clear meaning of this combination is that the swellable composition is not a liposome as claimed herein. The swellable composition is encapsulated in liposomes.

The Examiner further notes, “there is no EP patent with the number recited.” Applicant notes that in the Information Disclosure Statement provided, the publication number is seen on the actual document as EP 0375520.

Again, the Examiner has exceeded or misinterpreted the reference. The Examiner indicates that the microspheres, Page 3, bottom two thirds of page, “are made from even fatty substances such as fatty alcohols …” “These are lipophilic compounds …”

The Applicant refers to US Patent 6,287,549, Col. 3, line 51, to Col. 4, line 30. As clearly stated, “The microparticles comprising the chromophores may be dispersed in any medium … The dispersing phase may be a hydrophilic or hydrophobic composition …” Then the Examiner states, “These are lipophilic compounds (water repellants) …” According to the MedlinePlus Dictionary, these compounds have an affinity to lipids. The Examiner must be confused between lipophilic and hydrophobic. This patent then states that the microparticles in the dispersing***** medium may be applied with a solvent like water. See Col. 4, line 28.

Therefore, the statement by the Examiner, “liposomes themselves are microparticles and not that the polymers are within the liposomes.” is a non-sequitur. ???

Applicant does teach the use of the liposomes as the microparticles. ‘549 does mention that the microparticles can be polymers. Col. 3, line 33. This patent was incorporated by reference and therefore its teachings do provide guidance on the practice of the invention without undue experimentation.

Therefore, the Applicant respectfully asserts that this § 112 rejection is in error.

2. The Examiner rejected Claims 10 to 12 and 16 and 18 to 20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention for the reasons noted paragraph 4 of the office action.

Previous traverses are incorporated by reference.

As to claim 11, the Examiner state, “it is unclear as to what applicant intends to convey by ‘photosensitizer molecules, their derivates and their precursors used in photodynamic therapy’”

As stated in claim 11, “wherein said compounds/drugs are photosensitizer molecules, their derivatives and their precursors used in photodynamic therapy.” Unfortunately, the Examiner has taken the words out of context because the meaning present is clear: the compound/drugs are photosensitizer molecules; the compound/drugs are the derivatives of such; and that the compound/drugs are the precursors of such also. As defined by the Applicant on Page 9, lines 8 to 10, “compound/drugs” mean any molecules used in cosmetic and/or pharmaceutics fields, including all photosensitizer molecules, their derivatives, and their precursors used in photodynamic therapy.” Therefore, the Examiner’s limitation of just “photosensitizer molecules” is not proper by the Applicant’s definition. ??bit off mark??

Claim 11 is directed at the compound/drugs which is far boarder than just “photosensitizer molecules.” Therefore, Applicant suggests that the combination noted in claim 11 is proper and clear based upon the definition provided.

As to claim 12, Applicant again points to the definition of the term, “cosmetically and/or pharmaceutically acceptable composition” on page 8, lines 21 to 25. The answer to the Examiner’s question is noted on Page 9, line 25, “commensurate with a reasonable benefit/risk ratio” as to the composition.

As to claim 16 which is dependent off of claim 13, the swellable composition is noted as a polymer and the polymer is encapsulated and therefore the swellable composition is encapsulated. Did the applicant state that the polymer is a microsphere in claims 1, 13 or 16. No. Claim 17 noted merely that the polymer may be microspheres. Claim 17 has been cancelled to prevent this limitation being read into claims 1, 13 and 16 by the Examiner. The applicant does not limit the location of the swellable composition to microspheres in claims 1, 13 and 16. It could be a liposome. Page 9, line 3. The Examiner states, “There is an inadequate description of this expression in the specification.” Reference is made to Page 5, line 27 to 28: “The swellable composition can be polymers … encapsulated in microspheres or liposomes, and/or form microspheres.”

As to claim 19, the Examiner notes, “unclear … ‘swelling composition is covered … vertical swelling.’” The meaning is related on Page 9, lines 26 to 28. Applicant desires to limit

the vertical swelling in the hair follicle and this is done by the application of a plate, a film, a dressing, etc., to force the swelling more into the horizontal direction within the follicle itself to force the follicle to remain open after the removal of the hair. The meaning is clear in light of the specification as noted.

3. Claims 1-2 and 8-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48716, Sumian et al., of record (also US Patent 6,287,549) for the reasons noted in paragraph 6 on page 6 of the office action.

Previous traverses are incorporated by reference.

Sumian et al. disclose the use of microparticles to destroy the hair follicle by laser light to create a shock wave. Col. 4, lines 44 to 49. The microparticles are applied to the skin by massage, for example, with optional hair removal. Col. 4, lines 8 to 13. The composition must be removed before the application of laser energy. Col. 4, lines 13 to 18. There is no mention in Sumian et al. to keep the hair follicle open because of the traveling shock wave.

As noted in claim 1 of the present invention, in step 2, a “compound/drug” and a “swellable composition” are applied. The swellable composition insures that the pore remains open for the penetration of the compound/drug into the follicle. The compound/drug may itself destroy the hair follicle, but other means are allowed such as the use of photosensitizer compositions with laser light as noted in the dependent claims.

The claims of Sumian et al. being 4 steps involve the removing of the composition from the skin and the application of laser energy. This is not required in claim 1 of the present invention. Also, Sumian et al. apply laser radiation to the composition to destroy the follicle by a shock wave. This is not the process used in claim 1 of the present invention and this is the reasons for its non-inclusion in claim 1.

The definition of the “compound/drug” is noted on Page 9, lines 8 to 10, and includes photosensitizer molecules. The “swellable composition” is defined on Page 8, line 26, to Page 9, line 7. In one preferred embodiment it may be a liposome, but the key requirement is that the material having swelling properties to hold open the follicle lumen. At no point does the Applicant claim that the swellable composition is a liposome.

It is therefore argued that indeed the process of named WO is not the same steps.

Claim 2 presents the claim where the composition includes the compound/drug. This happens when, for example, the liposome being the swellable composition encapsulates the polymers.

As to claim 5, Sumian et al. do not disclose any swelling in the area of the hair follicle nor is this an issue. Claim 8 has been cancelled.

As to claim 9, Sumian et al. certainly does not disclose the step of occluding the hair follicles upon the application of the compound/drug and swellable composition. Clearly claims 1 and 8 are patentable together.

4. Claims 1-2 and 8-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer for the reasons noted in paragraph 7 on page 7 of the office action.

Previous traverses are incorporated by reference.

Schaefer (US Patent 5,292,512) details a composition related to skin treatment such as acne. The composition is composed of microspheres with an active product therein. The solvent used is noted as a swelling agent for the microspheres themselves. Col. 4, lines 55 to 68. The composition is applied to the skin and enters the pilosebaceous orifices. The microspheres must have a given range to enter into these orifices of 3 to 10 μm . The microspheres may be made of polymers and other materials noted on Col. 3, lines 21 to 47. The active products are noted on Col. 3, line 48 to Col. 4, line 15. The polymer material is noted as a swellable composition on Col. 4, line 65, as a result of the swelling agent which is a solvent.

As contrasted with the present invention, Schaefer does not remove the hair and does not apply the swellable composition for the purpose of holding opening the hair lumens for the infusion of chemicals therein.

5. Claims 1 to 2 and 8 to 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48716, further in view of Li (US Patent 5,914,126) and/or Nakamura, 1980 for the reasons noted on Page 7 of paragraph 8.

Previous traverses are incorporated by reference.

Li et al. disclose the application of the liposomes onto mice skin which was shaved and then covered to immobilize and to prevent evaporation. Col. 41, line 65, to Col. 42, line 5.

From the text, it is clear that the removal of hair was for the purpose of harvesting the skin for examination and also the band-aid was for the purpose of preventing removal and evaporation as noted. Col. 42, lines 1 to 13. Neither of these features were of concern in the present invention. The hair was removed to allow better penetration of the compound/drug into the lumen and covering of the swellable composition was for increasing the force of expansion laterally to force the lumen to stay open after the hair is removed.

Nakamura et al. disclose the use of a tape having a composition thereon for application to a test area on mice skin. The tape is used to mechanically hold the composition against the skin which is clearly different than the present invention. Obviously, the removal of hair on the test mice was for improving the contact area of the composition on the skin. Neither of the features were of concern in the present invention as noted above. Nakamura and Li both being directed at testing on the skin of mice; not as a way to more permanently keep hair from growing in the treated area of skin.

In the present invention, hair removal provides for a better opening for the penetration of the compositions into the lumen of the hair follicle. The application of a cover over the swellable composition, again, provides for lateral expansion to hold the lumen opening against the natural forces that close a lumen when the hair is removed.

6. Claims 1 to 2 and 8 to 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer cited above, further in view of Li (US Patent 5,914,126) and/or Nakamura, 1980 for the reasons noted on Page 8 of paragraph 9.

Previous traverses are incorporated by reference.

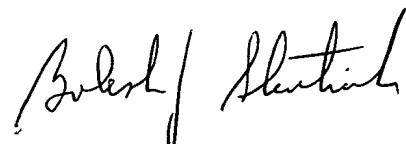
Schaefer discloses the use of composition for topical application having microspheres of polymers, for example, of a particular diameter range so as to be able to enter into the hair lumen. An active material is placed on or in the microsphere. The fact that the polymer is swellable is noted on Col. 4, lines 55 to 68. The fact that the microspheres are of a particular diameter clearly teaches away from the swellable nature of the composition because this would increase the diameter. As noted on Col. 4, lines 65 to 68, the swelling agent can be used to convert the material into a gel. No other purpose is disclosed for use of the swelling agent to make the polymers swell.

The relevant teachings of Li et al. and Nakamura et al. are noted above as well as the reasons why they are not applicable to the present invention.

The applicant believes that the rejections under 35 U.S.C. 103(a) are not correctly applied in that mere usages of similar words is taken to imply features that are not even discussed in the cited references and are merely used to generate statements that use hindsight reconstruction for applying these words to the present invention. The treatments disclosed and claimed were not about hair removal and improvements to keep hair from growing in the treated areas for longer times or ever after treatment. Testing drugs on mouse skin to determine skin sensitivity or efficacy of a drug has no direct or indirect connection or value to practitioners looking to improve a person's image by 'permanently removing' unwanted hair in the chosen skin sites. Those skilled in the art of the latter would not consider worthwhile any animal work done for the former reasons.

With these changes and remarks it is believed that the disclosure is now in condition for allowance. Reconsideration is respectfully requested. An early and favorable response is earnestly solicited. If necessary, a telephone call would be appreciated to discuss any further final changes to be made to render the claims allowable. Thank you.

Respectfully submitted,



Bolesh J. Skutnik, PhD, JD
Reg. No. 36,347
Attorney for Applicants

Fax: (413) 525-0611

Dated: September 9, 2005

CeramOptec Industries, Inc.
515 Shaker Road
East Longmeadow, MA 01028
Phone: (413) 525-8222

BJA/sec